FACET TECHNOLOGIES

K140568

510(k) Summary

As required by the Safe Medical Devices Act (SMDA) of 1990 and in accordance with 21 CFR § 807.92, Content and Format of a 510(k) Summary, the following safety and effectiveness information is provided below:

Date Prepared:	March 3, 2014
Submitter:	Facet Technologies, LLC 112 Town Park Dr. Suite 300 Kennesaw, GA 30144 Facility Registration Number: 2082882
Company Contact Person:	Jennifer Register Senior Regulatory Affairs Specialist Phone: (770) 590-6455 FAX: (770) 590-6412 Email: jennifer_register@facettechnologies.com
Common Name of Device	Insulin Pen Needle
Proprietary Name	CareFine™ Pen Needle with QuintaPoint™ and SuperPoint™
Classification Name	Hypodermic Single Lumen Needle
Classification Regulation	21 CFR §880.5570, Class 2
Panel	80 General Hospital
Product Code	FMI

[807.92(a)(3)]

Predicate Device:

CareFine™ Pen Needle (K133100)
Manufactured by Facet Technologies, LLC

[(807.92(a)(4)]

Description of Device:

CareFine™ Pen Needles are single use, sterile medical devices designed to be used in conjunction with pen injectors and pen cartridges for the subcutaneous injection of insulin. Pen needles are used by consumers, caregivers and health care professionals. They are offered in various gauge sizes (29G, 30G, 31G and 32G) and lengths (4mm, 5mm, 6mm, 8mm, and 12.7mm). CareFine™ Pen Needles are sterile by EtO terminal sterilization, and they are non-toxic and non-pyrogenic.

The pen needle assembly consists of a doubled-ended cannula that is assembled into an injection molded hub using adhesive. The hub has internal threads, which allow it to be screwed onto the pen injector device. This allows the cartridge end of the cannula to penetrate through the rubber septum of the cartridge. The patient-end and the cartridge-end of the cannula are lubricated using a silicone based lubricant for ease of injection and rubber septum penetration.

An injection-molded inner shield is assembled over the patient-end of the cannula to protect the point from damage and accidental needle-sticks. This needle assembly is inserted into a protective injection-molded outer cover and sealed with a peel-away label to provide a sterile barrier and tamper evident seal. The peel-away label is pre-printed with information, which includes the lot number, needle gauge and needle length.

The individual needle assemblies are packaged in cartons, and placed into shippers with appropriate labeling. The shipper cases are palletized and sterilized to a SAL of 10^{-6} by EtO terminal sterilization.

The purpose of this Special 510(k) is to request modification to our CareFine™ Pen Needles to include colored inner needle shields to distinguish the needle length.

It is also Facet's intent to notify the Agency of non-significant changes to the cannula point bevel geometry. There are two additional needle point geometries being offered: a 5 bevel configuration corresponding to the QuintaPoint™ marketed name, and a second needle tip geometry identified as the SuperPoint™.

The intended use for the modified device remains the same as the predicate device.

[(807.92(a)(5)]

Intended Use / Indication for Use:

The CareFine™ Pen Needle is intended for use with a pen injector device for the subcutaneous injection of insulin.

[(807.92(a)(6)]

Technological Characteristics:

The CareFine™ Pen Needle with colored needle shields is identical in composition to the CareFine™ Pen Needle. The only differences are the needle point and colorant additive to the inner needle shield to distinguish needle length.

The CareFine™ Pen Needle with colored inner needle shields are equivalent given that they:

- Have the same indication for use,
- Do not have any labeling changes that affect the intended use of the device,
- Do not alter the fundamental scientific technology,
- Incorporate the same basic design
- Use the same operating principles,
- Are manufactured from the same materials,
- Are sterilized with a resulting SAL of 10^{-6}, and
- Are packaged using same unit and case materials.

Based on the comparisons described above to the predicate comparator device, the CareFine™ Pen Needle with colored inner needle shields do not raise any new issues of safety and effectiveness.

[(807.92(b)(1)]

Non-Clinical Performance Data:

Non-clinical performance data was performed and submitted with The CareFine™ Pen Needle Traditional 510(k) (K133100). The CareFine™ Pen Needle with colored needle shields is manufactured in accordance with the requirements of the current Good Manufacturing Practices for Medical Devices and follows 21 CFR Subpart C "Design Controls". All verification and validation activities identified by the risk analysis were performed to demonstrate continued conformance with applicable conformance standards. The principle device demonstrated equivalent performance to the predicate device during testing.

Based upon the risk analysis the following tests were performed:

Cytotoxicity	Per ISO 10993-5
Sensitization	Per ISO 10993-10
Intracutaneous Reactivity	Per ISO 10993-10
Acute Toxicity	Per ISO 10993-11
Hemocompatibility	Per ISO 10993-4 ASTM F756-8
Needle Shield Assembly Strength	Internal Test Method

[(807.92(b)(2)]

Clinical Performance Data:

Clinical data is not required.

[(807.92(b)(3)]

Conclusion:

Based on the design equivalency and the verification and validation activities performed, Facet Technologies, LLC has determined that CareFine™ Pen Needle family are equivalent to the predicate comparator devices currently cleared for marketing in the United States. Differences between the devices do not raise any significant issues of safety and effectiveness.

[(807.92(d)]

Other Information:

None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 13, 2014

Facet Technologies, LLC
Ms. Jennifer Register
Senior Regulatory Affairs Specialist
112 Town Park Drive
Suite 300
Kennesaw, GA 30144

Re: K140568
Trade/Device Name: CareFine™ Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: April 15, 2014
Received: April 17, 2014

Dear Ms. Register:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K140568

Device Name
CareFine™ Pen Needle

Indications for Use *(Describe)*
The CareFine™ Pen Needle is intended for use with a pen injector device for the subcutaneous injection of insulin.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman
Date: 2014.05.12 16:06:34 -04'00'

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